

[DO NOT PUBLISH]

IN THE UNITED STATES COURT OF APPEALS  
FOR THE ELEVENTH CIRCUIT

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No. 16-17356  
Non-Argument Calendar

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D.C. Docket No. 1:15-cv-21826-KMM

MAGGIE O. TSAVARIS,

Plaintiff-Appellant,

versus

PFIZER, INC., et al.,

Defendants,

BRECKENRIDGE PHARMACEUTICAL, INC.,  
a Delaware corporation,

Defendant-Appellee.

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Appeal from the United States District Court  
for the Southern District of Florida

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(November 21, 2017)

Before WILLIAM PRYOR, ROSENBAUM and FAY, Circuit Judges.

PER CURIAM:

Maggie Tsavaris appeals *pro se* the denial of her motion for leave to file a second amended complaint of negligence against Breckenridge Pharmaceutical, Inc. Tsavaris, with the assistance of counsel, moved for leave to amend under Federal Rule of Civil Procedure 15 after the district court entered judgment against her first amended complaint as preempted by federal law. We affirm.

In her first amended complaint, Tsavaris alleged claims of negligence, negligent misrepresentation, and strict liability against Breckenridge, a drug manufacturer. Tsavaris alleged that she developed breast cancer after she ingested the generic version of the drug Activella, a hormone replacement therapy drug. The district court ruled that Tsavaris's complaint was preempted by federal law because Breckenridge could not have undertaken the actions that Tsavaris alleged that it should have performed without violating federal laws that prohibited the company from changing the formulation of or the labeling approved for the brand name drug. *See Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013); *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011); *Guarino v. Wyeth, LLC*, 719 F.3d 1245, 1248 (11th Cir. 2013).

Tsavaris moved “that [the] Court freely give leave” to amend her complaint under Federal Rule of Civil Procedure 15(a)(2). Tsavaris's proposed second

amended complaint alleged that she would not have been harmed had Breckenridge not “failed in its federally mandated duty,” under “21 U.S.C. § 355(e)[ and] (k),” to notify the Federal Drug Administration of scientific studies that connected the use of the generic version of Activella to breast cancer. Tsavaris argued that the denial of her amendment would be “inconsistent with the spirit of the Federal Rules” to “serve the Court and the parties’ interest in efficiently addressing [her] claims.” Tsavaris also argued that her “amendment cannot be considered an exercise in futility . . . because [it] is based squarely on this Court’s Order and ‘present[s] a viable state tort negligence claim that falls outside the scope of federal preemption.’”

The district court denied Tsavaris’s motion on the ground that its judgment “le[ft] no room for Tsavaris to renew her negligence claim against Breckenridge.” The district court rejected as “misguided” Tsavaris’s reliance on a sentence describing her burden to state a claim of negligence “as giving her leave to refile her negligence claim against Breckenridge.” The sentence relied on by Tsavaris stated, “To present a viable state tort negligence claim that falls outside the scope of federal preemption, [Tsavaris] must allege that Breckenridge: (1) breached its duty to exercise reasonable care and (2) could have taken actions in line with its federal law obligations that would have also allowed it to discharge its duty to exercise reasonable care.” Tsavaris “read[ ] the . . . [sentence] out of context,” the

district court stated, because it had “go[ne] on to state: ‘Breaking [Tsavaris’s] negligence claim down, it is clear that there is no action that Breckenridge could have taken to discharge its duty under state negligence law without violating federal law.’”

We review the denial of Tsavaris’s postjudgment motion for leave to amend for abuse of discretion. *Jacobs v. Tempur-Pedic Int’l, Inc.*, 626 F.3d 1327, 1345 (11th Cir. 2010).

The district court did not abuse its discretion when it denied Tsavaris’s postjudgment motion to amend. Rule 15 governs the procedures for amending and supplementing pleadings. Fed. R. Civ. P. 15. But that rule “has no application once the district court has dismissed the complaint and entered final judgment for the defendant. Post-judgment, [a] plaintiff may seek leave to amend if [s]he is granted relief under Rule 59(e) or Rule 60(b)(6)” of the Federal Rules of Civil Procedure. *Jacobs*, 626 F.3d at 1344–45 (quoting *U.S. ex rel. Atkins v. McInteer*, 470 F.3d 1350, 1361 (11th Cir. 2006)) (citations omitted). Tsavaris failed to identify either “newly-discovered evidence [that supported her claim] or manifest errors of law or fact” in the judgment, as required to obtain relief under Rule 59(e), *see id.* at 1344 (quoting *Arthur v. King*, 500 F.3d 1335, 1343 (11th Cir. 2007)), or a “justification so compelling that the district court was required to vacate its order” under Rule 60(b), *see Cano v. Baker*, 435 F.3d 1337, 1342 (11th Cir. 2006). Tsavaris did not

dispute that the allegations of negligence in her first amended complaint were preempted by federal law, and she could not use her postjudgment motion to “raise [her] argument [about the failure of Breckenridge to comply with section 355] . . . that could have been raised prior to the entry of judgment,” *Jacobs*, 626 F.3d at 1344 (brackets omitted). Tsavaris failed to abide by the Rules of Civil Procedure when requesting leave to amend her complaint.

Even if we were to assume that Tsavaris had satisfied the procedural rules governing the amendment of her pleading, we cannot say the district court abused its discretion by denying Tsavaris’s motion. Any amendment of her complaint would have been futile. Tsavaris’s proposed second amended complaint is also preempted by federal law. *See Buckman Co. v. Plaintiffs’ Legal Committee*, 531 U.S. 341 (2001); *Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319 (11th Cir. 2017).

Preemption occurs when the federal government has exclusive power to punish an individual or entity for a violation of a federal statute or regulation. *See Buckman*, 531 U.S. at 348. In *Buckman*, the Supreme Court concluded that a plaintiff’s complaint about the violation of state law based on fraudulent representations made by a medical device manufacturer to obtain approval for orthopedic bone screws was preempted by federal law that empowered the Federal Drug Administration to punish and deter fraud perpetrated against it. *Id.* at 347–52.

And recently, based on *Buckman*, we held that preemption prohibits plaintiffs from bringing private causes of action to enforce a duty owed to a federal agency. *Mink*, 860 F.3d at 1327, 1330. In *Mink*, the plaintiff’s complaint of negligence was premised on the alleged failure of a manufacturer of a hip joint replacement system to report adverse events involving its system to the Administration. *Id.* at 1323–24. We concluded that *Mink*’s complaint, like the complaint in *Buckman*, was preempted because it was based on “alleg[ations] a manufacturer failed to tell the FDA those things required by federal law.” *Id.* at 1330.

Tsavaris, like the plaintiffs in *Buckman* and *Mink*, complains of a violation of a federal reporting duty owed to a federal agency, not to her. Tsavaris complains that Breckenridge, a federally regulated drug company, was negligent for failing to fulfill its duty to report findings about its product to the Administration. Her complaint is based entirely on a provision of the federal Drug Price Competition and Patent Term Restoration Act that requires Breckenridge to submit “data relating to clinical experience and other data or information, received or otherwise obtained” about the safety, effectiveness, or labeling of its drug to the Administration, 21 U.S.C. § 355(k). The premise of Tsavaris’s complaint is that Breckenridge was negligent because it violated section 355(k), not because it failed to satisfy a duty of care owed to her under state law. *See Buckman*, 531 U.S. at 352 (differentiating between the preempted complaint, which was drawn “solely from

the violation of FDCA requirements” and a complaint based “on traditional state tort law principles of the duty of care owed” by a defendant). Because Tsavaris seeks to enforce a duty owed to a federal agency and her cause of action would not exist in the absence of that duty, her proposed second amended complaint is preempted.

We **AFFIRM** the denial of Tsavaris’s motion for leave to amend.